AMERICAN SOCIETY FOR
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

TO: Division of Dockets Management

SUBJ: Docket No. 2004D-0466; Draft Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act

The American Society for Clinical Pharmacology and Therapeutics (ASCPT) commends the FDA for developing the new guidance for the dietary supplement industry titled, "Substantiation for Dietary Supplement Claims Made Under Section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act," which was released in draft form Nov. 9, 2004. This guidance document should help to ensure that the best available evidence is submitted to the FDA in support of proposed claims. Such activities will facilitate appropriate decisions regarding the approval or disapproval of dietary supplements. If a claim is disapproved based on inadequate evidence, the guidance will help the applicant design studies that could provide acceptable supporting evidence.

Dietary supplements are regularly used by a large number of Americans with the belief that they improve human health and well-being. Most consumers also believe that dietary supplements are subject to significant governmental regulations and have undergone extensive review by your agency to ensure their safety and efficacy. Quite to the contrary, DSHEA assumes that supplements, unlike drugs and food additives, are safe and are thus exempt from laws related to proving compound safety. These regulations have the potential to severely limit the control that the FDA can exert over the dietary supplement industry to ensure product safety.

ASCPT supports FDA plans to substantiate that dietary supplements marketed prior to DSHEA do not pose significant health risks to consumers. Improving safety enforcement via collaborations with other government agencies is the first step in a process to provide much needed oversight of adverse reactions associated with these agents. Plans to improve detection of adverse events through more careful monitoring of databases within and outside the government will contribute, as will efforts to enhance public awareness of the need to report adversities.

Although DSHEA does not require adverse event reporting by dietary supplement manufacturers or distributors, ASCPT supports FDA attempts to have them voluntarily do so. Further, ASCPT favors additional, more stringent monitoring of adverse events including the initiation of a mandatory adverse reporting system for supplement manufacturers and distributors.

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A focus of the current enhanced regulatory proposal by the FDA is to require that NDI (new dietary supplements marketed after 1994) regulations be more vigorously enforced with respect to safety and that the manufacturer and distributor supply the FDA with adequate information to reasonably evaluate safety. Should such information not be provided, the FDA would have the authority to deem the product unsafe. ASCPT strongly agrees with this regulatory strategy and believes that it can only serve to enhance the safety of new dietary supplements for the consumer.

We urge FDA to finalize its work on current good manufacturing practices (cGMP) for dietary supplements to ensure supplement quality and safety. These regulations are long overdue. Publication of a final rule on dietary supplement cGMP is urgently needed, and should be followed by prompt implementation and strict enforcement.

We applaud FDA proposals to more carefully regulate information on dietary supplement labels. Manufacturers and distributors frequently make label claims related to the use of substances to treat disease and provide label statements regarding structure and function relationships, many of which are unsubstantiated. Attempts to more carefully regulate these inaccurate labeling claims are supported by ASCPT, and we encourage the FDA to take action against improperly labeled agents.

In summary, despite the limitations of DSHEA to regulate the safety of dietary supplements, ASCPT believes that the recent FDA proposals are a step in the right direction and will further provide consumers with safer and more efficacious agents.

Sincerely,

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